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Results of treatment of myopia progression by the method of cryogenic scleroplasty

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AIM: To evaluate the results of the effectiveness of cryogenic scleroplasty.

MATERIALS AND METHODS: 184 children (313 eyes) (mean age 11,72 ± 3,76 years) with moderate and high progressive myopia were examined before and after cryogenic scleroplasty (main group) and Pivovarov's scleroplasty (control group).

RESULTS: A smaller average annual difference in the spherical equivalent of refraction (ΔSE_{av}) and the average annual gradient of the axial length (ΔAL_{av}) were recorded in the group of patients after cryogenic scleroplasty according to the data obtained during the two-year follow-up. ΔSE_{av} was –0,48 ± 0,45 diopters in the main group and –0,51 ± 0,34 diopters in the control group in children of the younger age subgroup (up to 9 years old); –0,35 ± 0,31 diopters in the main group and –0,69 ± 0,61 diopters in the control group (p = 0,047) in the older age subgroup (9 years and older). ΔAL_{av} in the main group was 0,15 ± 0,11 mm in children under 9 years of age, 0,31 ± 0,14 mm (p = 0,016) in the control group; 0,29 ± 0,18 mm and 0,34 ± 0,32 mm in children 9 years old and older, respectively.

CONCLUSIONS: The proposed technology of cryogenic scleroplasty has two surgical approaches in the lower-internal and upper-external parts of the eyeball; the scleroplastic material adheres evenly to the sclera, covers all four quadrants of the eyeball; it is fixed under the rectus muscles of the eye; at a 24-months follow-up period showed a good stabilizing effect.

Keywords: myopia progression; scleroplasty; axial length; refraction.

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Результаты лечения пациентов с прогрессирующей близорукостью методом криогенной склеропластики

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Цель исследования — оценка результатов эффективности криогенной склеропластики.

Материал и методы. Было обследовано 184 ребёнка (313 глаз) (средний возраст — 11,72 ± 3,76 года) с прогрессирующей миопией средней и высокой степени до и после проведения криогенной склеропластики (основная группа) и склеропластики по Пивоварову (группа контроля).

Результаты. Согласно полученным в ходе двухлетнего наблюдения данным, меньшая среднегодовая разница сфероэквивалента рефракции ($\Delta СЭ_{ср}$) и средний годовой градиент переднезадней оси ($\Delta ПЗО_{ср}$) зафиксированы в группе пациентов после криогенной склеропластики. У детей младшей возрастной подгруппы (до 9 лет) $\Delta СЭ_{ср}$ составила –0,48 ± 0,45 дптр в основной группе и –0,51 ± 0,34 дптр в группе контроля; в старшей возрастной подгруппе (9 лет и старше) — –0,35 ± 0,31 дптр в основной, и –0,69 ± 0,61 дптр — в группе контроля ($p = 0{,}047$). $\Delta ПЗО_{ср}$ у детей до 9 лет основной группы составил 0,15 ± 0,11 мм, в группе контроля 0,31 ± 0,14 мм ($p = 0{,}016$); у детей 9 лет и старше — 0,29 ± 0,18 мм и 0,34 ± 0,32 мм соответственно.

Заключение. Разработанная технология криогенной склеропластики имеет два операционных доступа в нижневнутреннем и верхненаружном отделах глазного яблока; склеропластический материал равномерно прилегает к склере, охватывает все четыре квадранта глазного яблока; фиксируется под прямыми мышцами глаза; при сроке наблюдения 24 мес. показала хороший стабилизирующий эффект.

Ключевые слова: прогрессирующая миопия; склеропластика; переднезадняя ось глаза; рефракция.

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INTRODUCTION

Progressive myopia is a known global medical and social problem. With an unfavorable course, the risk of serious complications, leading to a decrease in visual functions that are not amenable to optical and surgical correction, increases substantially [1–3]. An analysis of the results of 145 studies involving 2.1 million people predicts that by 2050 there would be a significant increase in the prevalence of myopia worldwide, and 938 million people would have high myopia [4].

At present, many theories attempted to explain the development and progression of myopia [5, 6]. Along with optical disorders, the involvement of the scleral factor in the pathogenesis of progressive myopia is undisputable. Through biomechanical studies, E. Iomdina reported that "… with the progression of myopia, the range of elastic deformations of the sclera is reduced, and even under physiological stress, its plastic deformations accumulate gradually, which results in irreversible stretching of the membranes and an increase in the axial length of the eye." Moreover, in the sclera, mainly in the region of the equator and the posterior pole, collagen metabolism is disturbed in the form of a decrease in the content of total collagen, an increase in the level of its soluble fractions, and a significant decrease in glycosaminoglycans and in the level of intra- and intermolecular cross-links that stabilize the connective tissue structures of the sclera [7]. Obviously, increase in the axial length (AL) and thinning of the sclera does not stimulate an adequate response from the more highly differentiated tunics of the eye (uvea and retina). They are not capable of such stretching and respond by a dystrophic process, and this eventually reduces all visual functions. Considering the polyetiologic nature of myopia, the treatment of progressive myopia should undoubtedly be comprehensive, including medical, functional (using visual training equipment), and optical methods of treatment and providing sclera reinforcement surgeries that improve the hemodynamics of the eye, generate a tissue biostimulating effect with the production of biologically active substances, activate collagen synthesis in the sclera, and increase its biomechanical stability [8–11]. Sclera reinforcement surgeries slow down the process of membrane stretching, slow down the progression rate, and delay or even prevent the development of dystrophic complications [8, 12]. Existing diversity of surgical sclera reinforcement methods [13–16] are indicative of the search for safe and effective methods to stabilize myopia progression.

This study aimed to analyze the efficiency of cryogenic scleroplasty in patients with progressive myopia.

MATERIALS AND METHODS

The study included 184 pediatric patients with progressive myopia aged 7–16 years (on average 11.72 ± 3.76 years), who underwent surgery at the Cheboksary branch of S.N. Fyodorov Eye Microsurgery Complex, interbranch scientific and technical complex of eye microsurgery of the Ministry of Health of Russia. Of these patients, 84 (45.65%) were boys and 100 (54.35%) were girls. The follow-up period was 2 years. The children underwent a comprehensive ophthalmological examination including ophthalmometry, refractometry, visometry with assessment of uncorrected and best corrected visual acuity before and after cycloplegia, optical biometry including AL registration with the IOL Master 500 biometer (Carl Zeiss, Germany), tonometry, biomicroscopy, ophthalmoscopy, examination of the fundus periphery with Goldman or Osher lenses, measurement of protein and inflammatory cells present in the anterior chamber fluid with the FC-2000 Tyndall meter (Kowa, Japan), as well as the study of ocular motility, determination of the character of vision with the Forbis apparatus, and Belostotsky–Friedman four-point color test.

The main group included 96 pediatric patients (167 eyes) who underwent cryogenic scleroplasty [17, 18], while the control group included 88 pediatric patients (146 eyes) who underwent standard Pivovarov scleroplasty. The study groups demonstrated comparable preoperative characteristics (Table 1). In 44 eyes (14% of the pediatric patients), prophylactic laser photocoagulation of the retina was previously performed for peripheral chorioretinal dystrophy.

According to the literature, AL increase is also noted in eyes with emmetropia, which is considered normal. The gradient of the increase in the AL of healthy children in the younger age group (7–8 years old) was 0.58 mm, and that in the older age group (9–10 years old) was 0.44 mm. In children with myopia, this indicator was nearly 2.5 times higher than that in children with emmetropia (1.55 ± 0.67 and 1.13 ± 0.32 mm, respectively) [18]. Given these values, for a correct assessment of changes in AL and refraction, children, taking into account standard values for their age, were distributed into two age subgroups (aged ⩽9 years and ⩾9 years).

Cryogenic scleroplasty involves the following:

1) Creation of an operative access in the lower nasal and upper temporal quadrants of the eyeball by separating the conjunctiva and Tenon's capsule from the sclera (Fig. 1)

2) After an exposure to liquid nitrogen for 10 seconds, the scleroplastic material is placed under the rectus muscles of the eye at an angle of 45° (Figs. 2 and 3).

In the lower nasal quadrant, the conjunctiva and Tenon's membrane are cut in layers perpendicular to the limbus. Tenon's capsule is separated from the underlying episclera to form a pocket under the lower and medial rectus muscles. A transplant (NEP MG, Moscow, TU 9398-001-29039336-2011), measuring 20 × 10 mm, is inserted under the lower rectus muscle after preliminary

Table 1. Study groups characteristic, *M* ± *m*
Таблица 1. Характеристика исследуемых групп, *M* ± *m*

Parameter	Main group	Control group
Total number of children (eyes)	96 (167)	88 (146)
Age, years	11.91 ± 2.78	11.66 ± 2.46
Spherical refraction, diopters	–5.85 ± 2.22 [–4.5; –11.5]	–5.67 ± 1.54 [–3.5; –10.75]
Cylindrical refraction, diopters	–1.04 ± 0.68	–0.96 ± 0.49
Axial length (AL), mm	25.98 ± 0.72 [24.40; 27.87]	25.83 ± 0.86 [24.01; 27.95]
Uncorrected visual acuity (UCVA)	0.04 ± 0.02	0.04 ± 0.02
Best corrected visual acuity (BCVA)	0.83 ± 0.19	0.84 ± 0.75

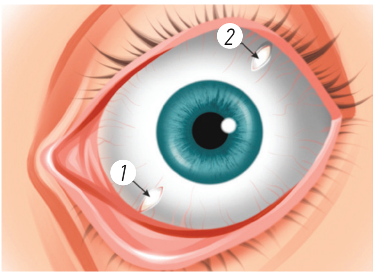

Fig. 1. Scheme of the location of the incisions of the conjunctiva and tenon capsule (left eye). *1* – in the inferio-nasal quadrant, *2* – in the superio-temporal quadrant
Рис. 1. Схема расположения разрезов конъюнктивы и теноновой оболочки (левый глаз). *1* — в нижне-носовом квадранте, *2* — в верхне-височном квадранте

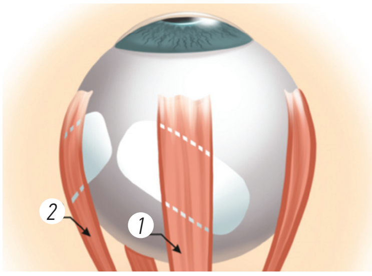

Fig. 2. Layout diagram transplants in the inferio-nasal quadrant (left eye). *1* – m. rectus inferior, *2* – m. rectus medialis
Рис. 2. Схема расположения трансплантатов в нижне-носовом квадранте (левый глаз). *1* — нижняя прямая мышца, *2* — медиальная прямая мышца

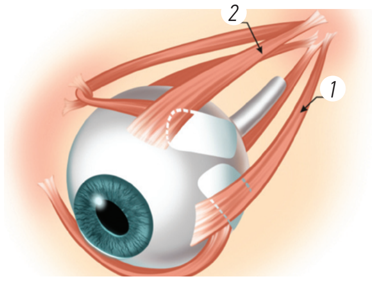

Fig. 3. Layout diagram transplants in the superio-temporal quadrant (left eye). *1* – m. rectus lateralis, *2* – m. rectus superior
Рис. 3. Схема расположения трансплантатов в верхне-височном квадранте (левый глаз). *1* — латеральная прямая мышца, *2* — верхняя прямая мышца

exposure to liquid nitrogen solution for 10 seconds. Through the same incision, the second scleroplastic material, after exposure to the liquid nitrogen solution, is inserted under the medial rectus muscle. In this case, the grafts were immersed behind the equator at an angle of 45° to the inferior and medial rectus muscles. The second incision of the conjunctiva is made in the superior temporal quadrant. The scleroplasty material exposed to liquid nitrogen solution is inserted under the lateral rectus muscle and immersed behind the equator at an angle of 45° to the muscle. Through the same incision, the next graft is placed behind the equator: its upper end is immersed under the superior rectus muscle, and the lower end is oriented in an oblique direction at an angle of 45° toward the lateral rectus muscle to close the area of attachment of the superior oblique muscle. Then, 8/0 buried sutures are applied to the conjunctival incisions (please see the video “Cryogenic scleroplasty,” https://journals.eco-vector.com/ov/copyeditor/downloadFile/59309/131708).

RESULTS AND DISCUSSION

All surgeries were performed without any complications. The postoperative period was practically uneventful, and there were no adverse reactions to the scleroplastic material used. In the first postoperative days, some pediatric patients had a minor photophobia and a moderate pain reaction at eyeball movements. The severity of these manifestations in the studied groups was nearly the same. In two patients of the main group (2%), minor conjunctival chemosis was registered. The vision remained binocular, and ocular movements were not restricted. Postoperative Tyndallometry parameters in the study groups remained within the normal limits; the average protein flux was 3.6 ± 0.07 f/ms in the main group and 3.4 ± 1.6 f/ms in the control group (normal values up to 5 f/ms).

AL and objective refraction could be considered as main indicators in the control of myopia progression [8]. Based on 2-year follow-up data, in pediatric patients of subgroup 1, the average annual difference in the spherical

Table 2. Average annual difference in the spheroequivalent of refraction. D (ΔSE_{av})
Таблица 2. Среднегодовая разница сфероэквивалента рефракции. дптр ($\Delta СЭ_{ср}$)

Subgroup	Follow-up	Main group	Control group
1	Before surgery	−4.84 ± 1.4	−4.91 ± 1.12
	1 year	−5.16 ± 1.34	−5.47 ± 1.13
	2 years	−5.60 ± 1.35	−5.84 ± 2.24
	D (ΔSE_{av})	−0.48 ± 0.45	−0.51 ± 0.34
		p = 1.0	
2	Before surgery	−6.25 ± 1.96	−6.01 ± 1.81
	1 year	−6.53 ± 2.10	−6.61 ± 1.83
	2 years	−6.78 ± 1.99	−6.96 ± 2.24
	D (ΔSE_{av})	−0.35 ± 0.31	−0.69 ± 0.61
		p = 0.047	

Table 3. Average annual gradient axial length (ΔAL_{av})
Таблица 3. Средний годовой градиент переднезадней оси ($\Delta ПЗО_{ср}$)

Subgroup	Follow-up	Main group	Control group	Children with emmetropia
1	Before surgery	25.12 ± 0.32	25.09 ± 0.58	–
	1 year	25.23 ± 0.65	25.47 ± 0.35	–
	2 years	25.40 ± 0.33	25.73 ± 0.29	–
	ΔAL_{av}	0.15 ± 0.11	0.31 ± 0.14	0.132 ± 0.02*
		p = 0.016		
2	Before surgery	25.96 ± 0.66	25.84 ± 1.55	–
	1 year	26.24 ± 0.21	26.26 ± 1.11	–
	2 years	26.55 ± 0.72	26.59 ± 0.29	–
	ΔAL_{av}	0.29 ± 0.18	0.34 ± 0.32	0.076 ± 0.07*
		p = 0.74		

*Sitka M.M. Sravnitel'nyj analiz razlichnyh sposobov dolgosrochnoj opticheskoj korrekcii progressirujushhej miopii u detej i podrostkov (Comparative analysis of Optical Correction Methods for Progressive Myopia in Children and Adolescents) [thesis], Moscow, 2018. 158 p.

equivalent of refraction (ΔSE_{av}) was −0.48 ± 0.45 diopters in the main group and −0.51 ± 0.34 diopters in the control group. In subgroup 2, the changes in ΔSE_{av} in the main group and control group were −0.35 ± 0.31 diopters and −0.69 ± 0.61 diopters, respectively (Table 2).

The average annual AL gradients (ΔAL_{av}) in pediatric patients of the subgroup 1 of the main group and of the control group were 0.15 ± 0.11 mm and 0.31 ± 0.14 mm, respectively. In subgroup 2, the values were 0.29 ± 0.18 and 0.34 ± 0.32 mm, respectively (Table 3).

The results of this study reveal that patients who underwent cryogenic scleroplasty demonstrated a lower average annual difference in the spherical equivalent of refraction (statistically significant in the subgroup aged ⩾9 years) and the average annual gradient AL (statistically significant in the subgroup aged ⩽9 years). Graft's exposure to liquid nitrogen solution keeps its shape, and the graft was not deformed during immersion and placement on the scleral surface. Its location under the muscles ensures a tight contact with the sclera and fixation of flaps. Local hypothermia after vascular spasm leads to vasodilatation with an increase in the intensity of local blood flow, and increases aseptic inflammation and immune response to transplantation and surgery. All of the above contributes to a more durable fusion of the graft with the sclera and ultimately determines the biomechanical stability of the "sclera–graft" complex.

CONCLUSION

In this study, the developed technique of cryogenic scleroplasty as surgical treatment for progressive myopia has two, instead of the traditional four, operative accesses, that is, approaches via the lower nasal and upper temporal parts of the eyeball. The scleroplastic material is fixed under rectus muscles, covers all four quadrants of the eyeball, and evenly adheres to the sclera. With a follow-up period of 24 months, a stabilizing effect was observed.

ADDITIONAL INFORMATION

Author contributions. N.P. Pashtaev created the concept and study design, performed scientific and methodological editing, surgical treatment, and provided final approval of the article version for publication. I.N. Grigorieva collected and processed the material, performed the diagnostic research, wrote the text, and reviewed the literature.

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